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Biotechnology

The EU Biotech Regulatory Process--A New Tower of Babel

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Report Highlights:

The EU's embrace of the precautionary principle underpins much of the current thinking on agricultural biotechnology and food safety in general. While the EU pays homage to implementing regulatory measures that are proportionate to the alleged risks, the reality for biotech and other food products is often far different. In a rather surprising admission, David Byrne, the EU's former Commissioner of Health and Consumer Protection recently commented:

"Germany sees the right to smoke as an issue of freedom, but how can you be free if addicted? It is extraordinary to me that you have states that express concern about genetically modified foods--when there's been no evidence of danger--but the same states are completely unconcerned about smoking, which we all know causes thousands of deaths each year."

Includes PSD Changes: No
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This past April the EU Commission's long awaited biotech legislation on traceability and labeling went into effect. The six year long search for a regulatory system intended to protect consumers and the environment, however, has yielded little in terms of a transparent, science-based approval process for biotech events. Over the last year 6 years, the EU has approved only two events--Syngenta's sweet corn (BT 11) and Monsanto's herbicide tolerant corn (NK 603).

When the Commission approved NK 603 on October 26, Margot Wallstrom, the EU's former Commissioner of Environment, had the following to say: "The NK 603 maize has been subject to a rigorous pre-market risk assessment. It has been scientifically assessed by the European Food Safety Authority as being as safe as any conventional maize. Its safety is, therefore, not in question, and neither is the question of user or consumer choice. Clear labeling provides farmers and consumers with the information they need to decide whether to buy the product or not. And robust post-marketing rules will ensure that the product can be traced and monitored when put on the market."

Regrettably many EU member states fail to share Wallstrom's sanguine view of the situation. While countries like Germany, Austria, and Italy have been among the most strident supporters of the current impractical and onerous regulatory system, the new labeling and traceability legislation championed by Wallstrom has still failed to overcome their misgivings.

Similarly, positive risk assessments issued by the European Food Safety Authority (EFSA) for several biotech events are regularly greeted with skepticism. The creation of EFSA in 2002 was the EU's much trumpeted initiative to instill consumer confidence after the BSE and dioxin food scandals.

For both BT 11 and NK 603, the Commission recommended that the member states authorize the marketing of these products based on the positive risk assessments issued. Despite this the member states failed to reach a qualified majority for or against approval, and the Commission then asked the Council of Ministers to come to a decision. After 3 months, the Council also deferred and sent the matter back to the Commission. The Commission then authorized the marketing of the two biotech events.

The Council of Minister's involvement in the approval process for biotech events can only be considered an aberration. Agriculture Ministers usually meet to review major issues such as CAP reforms or EU trade policy positions in the WTO Doha round. Typically, working level officials drawn from the member states consulting in a regulatory committee would make decisions on biotech events.

Several other biotech events are wending their way through this tortuous approval process. On November 29, 2004, Monsanto's corn rootworm (MON 863) failed to get a qualified majority and will now go to the Council of Ministers for the requisite 3 months. Like its predecessors, MON 863 was declared safe by EFSA on April 2, 2004.

In fact, EFSA declared it safe a second time after the Commission asked it to review data concerning the effects of feeding MON 863 to rats. Reportedly, one member state questioned EFSA's initial assessment on the basis of a study conducted by a scientist whose work had previously been discredited, thus prompting the second assessment. Nevertheless, this second EFSA endorsement failed to overcome the doubts of the member states who reportedly either abstained (Belgium, Czech Republic, Ireland, Spain, and Slovakia) or voted against (Austria, Cyprus, Denmark, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, and Slovenia).

Getting approval for a biotech event in the EU is more akin to a medieval morality play than a 21st century debate based on reason and science.

Recently, the WTO panel considering the U.S., Canadian and Argentine complaint against the EU's biotech moratorium granted the EU's request to call expert witnesses on biotechnology. Having thus bought itself additional time before the panel can reach a decision, the Commission will likely attempt to authorize further products over the objections of its recalcitrant member states in the hope of demonstrating that its regulatory system is working in a transparent and scientific manner.

The EU's embrace of the precautionary principle underpins much of the current European thinking on agricultural biotechnology and food safety in general. While the EU pays homage to implementing regulatory measures that are proportionate to the alleged risks, the reality for biotech and other food products is often far different.

In a rather surprising admission, David Byrne, former EU Commissioner of Health and Consumer Protection and one of the chief architects of the current biotech regulatory system made the following comments in a November 22 interview in the International Herald Tribune:

"Germany sees the right to smoke as an issue of freedom, but how can you be free if addicted?" he said, shaking his head. "It is extraordinary to me that you have states that express concern about genetically modified foods--when there's been no evidence of danger--but the same states are completely unconcerned about smoking, which we all know causes thousands of deaths each year."

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